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Attorney Docket: DX06022 US 01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re application of:

Martin OFT, *et al.*

Application No.: 10/797,157

Filed: March 9, 2004

For: USES OF IL-23 AGONISTS AND ANTAGONISTS; RELATED REAGENTS

Examiner: D. Jiang

Art Unit: 1646

Conf. No.: 4687

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 24, 2006

by: MELANIE LYONS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This is a response to the Restriction Requirement dated March 22, 2006. This response is timely filed within the one month period for reply by transmittal on Monday, April 24, 2006, the first business day following the one month deadline of Saturday, April 22, 2006.

I. Restriction Requirement

The Examiner restricted the application into eleven separate inventions:

I. Claims 1 in part, 3, 4 and 5 in part, 6, 7, 8 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an agonist of IL-23, wherein the agonist comprises an antibody, classified in class 424, subclass 130.1.

II. Claims 1 in part, 3, 4 and 5 in part, 7, 8 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an agonist of IL-23, wherein the agonist comprises a small molecule, classification depending upon the chemical entity of the small molecule.

III. Claims 1 in part, 3, 4 and 5 in part, 7, 8 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an agonist of IL-23, wherein the agonist comprises an anti-sense nucleic acid, classified in class 514, subclass 44.

IV. Claims 1 in part, 3, 4 and 5 in part, 7, 8 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an agonist of IL-23, wherein the agonist comprises a detectable label, classification depending upon the chemical entity of the agonist.

V. Claims 1 in part, 2, 3, 4 and 5 in part, 6, 7, 8 in part, 9, 10, 11 in part, and 12-14, drawn to a method of modulating tumor growth, or treating cancer with an antagonist of IL-23, wherein the antagonist comprises an antibody, classified in class 424, subclass 130.1.

VI. Claims 1 in part, 2, 3, 4 and 5 in part, 7, 8 in part, 9, 10, 11 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an antagonist of IL-23, wherein the antagonist comprises an extracellular region of IL-23R, classified in class 514, subclass 2.

VII. Claims 1 in part, 2, 3, 4 and 5 in part, 7,8 in part, 9, 10, 11 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an antagonist of IL-23, wherein the antagonist comprises a small molecule, classification depending upon the chemical entity of the small molecule.

VIII. Claims 1 in part, 2, 3, 4 and 5 in part, 7, 8 in part, 9, 10, 11 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an antagonist of IL-23, wherein the antagonist comprises an anti-sense nucleic acid, classified in class 514, subclass 44.

IX. Claims 1 in part, 2, 3, 4 and 5 in part, 7, 8 in part, 9, 10, 11 in part, 13 and 14, drawn to a method of modulating tumor growth, or treating cancer with an antagonist of IL-23, wherein the antagonist comprises a detectable label, classification depending upon the chemical entity of the antagonist.

X. Claims 15 and 17 in part, and 18, drawn to a method of diagnosis of a cancer with a binding compound specifically binding a polypeptide, and a kit for the diagnosis comprising the binding compound antibody, classified in class 435, subclass 7.1.

XI. Claims 15 in part, 16, and 17 in part, drawn to a method of diagnosis of a cancer with a binding compound specifically binding a nucleic acid, and a kit for the diagnosis comprising the binding compound, classified in class 435, subclass 6.

Applicants provisionally elect Group V, claims 1 in part, 2, 3, 4 and 5 in part, 6, 7, 8 in part, 9, 10, 11 in part, and 12-14, drawn to a method of modulating tumor growth, or treating cancer with an antagonist of IL-23, wherein the antagonist comprises an antibody, classified in class 424, subclass 130.1, for example, as discussed in the office action.

The Examiner further restricted the application to only one specific nucleotide or peptide sequence from Group A (SEQ ID NOs:1-6). For the reasons set forth below, Applicants traverse the restriction (in part), but nonetheless provisionally elect SEQ ID NO: 2.

Applicants traverse the restriction to only one member of Group A and request that examination proceed with respect to SEQ ID NOs: 2 and 4, which represent the amino acid sequences of human and mouse IL-23p19, respectively. SEQ ID NOs: 1, 3, 5 and 6 are no longer relevant due to the election of Group V in response to the preceding restriction requirement.

Although the Examiner asserts that "searching all of the sequences in a single patent application would constitute an undue search burden," the original Group A comprised only six sequences, which is less than the ten sequences suggested as normally constituting a reasonable number for examination purposes. M.P.E.P. §803.04 (although this section refers to nucleotide sequences, rather than protein sequences, the search burden would presumably be similar). The election of Group V further reduces the search burden to only two sequences, which sequences are homologous proteins from two species.

If the search and examination of all of the claims in an application can be made without serious burden, the examiner must examine them on the merits even though they include claims to independent or distinct inventions. M.P.E.P. §803. In light of the reduction in the number of sequences to be considered from six to two, and the consequent decrease in search burden, Applicants respectfully request that the restriction requirement be modified to allow examination of both IL-23p19 protein sequences (SEQ ID NOs: 2 and 4).

Applicants will address the issue of inventorship for the elected claims and amend inventorship appropriately if the elected restriction is made final.

Applicants reserve the right to file subsequent applications claiming the non-elected subject matter and do not waive any of their rights or abandon any non-elected subject matter. Since Applicants have fully and completely responded to the Restriction Requirement and have made the required election, this application is now in order for early action.

If the Examiner believes that a telephone conference would aid the prosecution of this case in any way, please call the undersigned.

Applicant believes that no additional fees are due with this communication. Should this not be the case, the Commissioner is hereby authorized to debit any charges or refund any overpayments to DNAX Deposit Account No. 04-1239.

Respectfully submitted,

Date: 24-April-2006

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